IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Attorney Docket No. 011738.00137

In re U.S. Patent Application of :	)	
	)	
Osorio *et al.*	)	
	)	Examiner: George C. Manuel
Application No. 10/688,214	)	
	)	Art Unit: 3762
Filed: October 15, 2003	)	
	)	Confirmation No.: 7258
For: Cycle Mode Providing Redundant	)	
Back-Up to Ensure Termination	)	
Of Treatment Therapy In A Medical	)	
Device System	)	

BRIEF ON APPEAL

MS: Appeal Brief- Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR §41.37, Appellant submits this Appeal Brief to the Board of Patent Appeals and Interferences in response to the Final Rejection mailed on January 15, 2008. The Commissioner is authorized to charge any fees owed or credit any overpayment of fees to Deposit Account No. 19-0733.

Page

I. Real Party in Interest

The real party in interest is Medtronic, Inc., the owner of the entire right, title and interest in and to the subject application.

II. Related Appeals and Interferences

There are no appeals or interferences related to the subject appeal.

III. Status of the Claims

Claims 1-23, which are involved in the appeal, stand finally rejected by an Office Action mailed January 15, 2008 and are found in the Appendix. No claim is allowed.

IV. Status of Amendments

No after final amendments were requested or are pending.

V. Summary of Claimed Subject Matter

The pending claims 1-23 are directed toward an apparatus and method for detection and the treatment of nervous system disorders with a cycle mode of operation to ensure that treatment therapy has stopped. (Specification, pg. 1, ¶ 2, ln. 2-3). Claims 1 and 11 are independent.

Turning to independent claim 1, which is directed toward a method providing redundant back-up, the step of "receiving an ON command signal to activate delivery of the treatment therapy to a patient" is recited and an embodiment of this is described in the specification on pg. 50, ¶ 156, ln. 4-5 and in Figure 24, element 2410. Next, the step "in response to receiving the ON command signal, initiating a cycle ON timer to operate for a predetermined cycle ON time" is recited and an embodiment of this is described in the specification on pg. 51, ¶ 157, ln. 10-12 and in Figure 24, element 2415. Then the step "delivering the treatment therapy to the patient" is recited and an embodiment of this is described in the specification on pg. 51, ¶ 157, ln. 10-12 and in Figure 24, element 2415. Next, the step "determining whether the cycle ON timer has expired prior to receiving an OFF command" is recited and an embodiment of this is described in the specification on pg. 51, ¶ 157, ln. 14-16 and in Figure 24, element 2425. Then the step "if the OFF command is received, turning off the treatment therapy" is recited and an embodiment of this is described in the specification on pg. 51, ¶ 157, ln. 17-19 and in Figure 24, element 2435. Next, the step "if the cycle ON timer has expired prior to receiving the OFF command, turning off the treatment therapy regardless of whether the OFF command signal is received" is recited and an embodiment of this is described in the specification on pg. 51, ¶ 158, ln. 1-3 and in Figure 24, element 2430.

Turning to independent claim 11, which is directed toward an apparatus, the feature "a

first component capable of transmitting an ON command signal to activate delivery of the treatment therapy to a patient and an OFF command signal to terminate delivery of the treatment therapy to a patient" is recited and an embodiment of this is described in the specification on pg. 50, ¶ 155, ln. 11-13 and shown in Figure 12, element 23. Then the feature "a second component capable of receiving the ON command signal to deliver the treatment therapy to the patient and capable of receiving the OFF command to terminate delivery of the treatment therapy to the patient" is recited and an embodiment of this is described in the specification on pg. 50, ¶ 155, ln. 9-11 and in Figure 1, element 107 and Figure 11, element 1100. Next, the feature "a cycle ON timer within the second component, wherein, in operation, the cycle ON timer is activated in response to the second component receiving the ON command signal" is recited and an embodiment of this is described in the specification on pg. 50, ¶ 156, ln. 1-9. Then the feature "wherein the second component is also responsive to the cycle ON timer for causing termination of delivery of the treatment therapy in the event that the second component does not receive an OFF command from the first component for a period longer than a predetermined cycle ON time and during which time the treatment therapy is being delivered" is recited and an embodiment of this is described in the specification on pg. 50, ¶ 156, ln. 1-9.

Regarding dependent claim 15, which depends from claim 11, the feature "wherein the second component is an implanted device" is recited and an embodiment of this is described in the specification on pg. 50, ¶ 155, ln. 4-8 and in Figure 11, element 1100.

VI. Grounds of Rejection to be Reviewed on Appeal

Claims 1-14 and 16-23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,639,234 to Badura *et al.* ("Badura") in view of U.S. Patent No. 3,916,923 to Branton ("Branton"). Claim 15 was rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,540,681 to Strul *et al.* ("Strul") in view of Branton. The rejections of claims 1-23 are being appealed.

VII. Argument

The discussion below, unless otherwise noted, addresses the rejected independent claims 1, 11 and dependent claims 2-10 and 12-23. The initial discussion regarding the incorrectness of the rejection applies to all the pending claims 1-23. In addition, the rejection of independent claims 1 and 11 may be reversed for substantially similar additional reasons and thus are addressed together for purposes of this appeal. Claim 15 was rejected under a different combination of references and therefore additional reasons for why the rejection of claim 15 should be reversed are addressed separately. The rejection of the remaining dependent claims should be reversed for at least the reasons supporting reversal of the rejection of the independent claims from which they depend and for the additional limitations recited therein.

A. The Rationale for Combining Branton with either Badura or Strul is Conclusory and Lacks a Logical Basis, Thus the Rejection of the Pending Claims 1-23 is Not Supported.

The pending claims 1-23 were rejected in view of the combination of either Badura and Branton or Strul and Branton. In both cases, the primary cited references admittedly fail to disclose the feature "in response to receiving the ON command signal, initiating a cycle ON timer to operate for a predetermined cycle ON time" recited in claim 1 or the feature "a cycle ON timer within the second component, wherein, in operation, the cycle ON timer is activated in response to the second component receiving the ON command signal" recited in claim 11. The Examiner suggested, however, that Branton corrected the deficiency in either reference by disclosing a cycle ON timer that was responsive to an ON signal and that it would have been obvious to modify the primary references to ensure safety. In particular, the Examiner suggested that safety was the motivating factor to combine Badura and Branton:

> One of ordinary skill in the art would have found it obvious to use the initiating cycle ON timer that is responsive to receiving the ON command signal as taught by Branton for providing safety in addition to the redundancy means disclosed in the device of Badura et al for ion beam therapy.

Final Office Action, pg. 3. Similarly, the Examiner suggested that safety provided the motivation to combine Strul and Branton:

> One of ordinary skill in the art would have found it obvious to use the initiating cycle ON timer that is responsive to receiving the ON command signal as taught by Branton for providing safety to the device disclosed in Strul et al.

Final Office Action, pg. 5. While safety might normally be a reasonable rationale for certain combinations, here the alleged improvement in safety is entirely conclusory, lacks a logical underpinning and is not supported.

As an initial matter, the rationale lacks any support other than a conclusory statement made by the Examiner. This is direct conflict with the clear guidelines provided by the Supreme Court that an explicit analysis of factors such as "interrelated teachings of multiple patents" and "the effects of demands known to the design community or present in the marketplace" and "the background knowledge possessed by a person having ordinary skill in the art" must be made. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740-1741 (2006). For example, there is no support for the suggestion that Branton and Bandura can be considered to have interrelated teachings. Indeed, given the fact that Bandura is directed toward an ion beam treatment system and Branton is directed toward using an analog timer motor for a sanitizing device in conjunction with a milking system, there seems to be no support for the suggestion that the references having any interrelated subject matter. Notably, there has been no support provided for why a person of skill in the art of ion beam treatment devices would look to a sanitizing device for a milking system.

In addition to the disparate technologies, the system of Branton discloses a fail safe timer

motor 86 that is used to ensure that in the event of a failure in a primary timer motor, power to the entire sanitizing system will be shut down. Branton, Col. 7, ln. 54 – Col. 8, ln. 13. No support has been provided for how or why such a timing motor would be used in Badura. For example, the Examiner did not even address how reliable the timer motor of Branton would be or its precision in stopping after the desired period of time. In this regard, Applicants respectfully submit that the precision required in an ion beam treatment system would appear to be at least an order of magnitude greater than that required for a timing motor in a sanitizing device for a milking system. Indeed, given the relative crudeness of the timing motor, it does not seem that the analog timing motor of Branton could be safely used in Badura under any circumstances. Thus, the suggestion that the timing motor of Branton would improve the safety of Badura has not been supported.

A similar problem exists for the combination of Strul and Branton because Strul is directed toward a device that uses RF for the purposes of tissue ablation. As would be expected, Strul uses a digital processor to control delivery of RF and Strul discloses that the microprocessor provides for continuous monitoring of power, current, voltage, temperature, impedance and battery level while allowing the user to set the power set point, the temperature set point and the timer set point. Given the functionality of the digital processor, it is unclear how use of a timer motor such as disclosed by Branton (which was basically intended to provide a back-up for another timer motor) could make the system of Strul safer. Notably, the Examiner provided no support for the suggestion that the system of Strul would actually benefit from use of a timer motor or even that the overall concept would make the system of Strul safer given that addition of a secondary programming loop on the same digital processor would be unlikely to increase safety.

In addition, the concept behind the disclosure of Branton appears to be a recognition that timer motors, being mechanical devices, can fail and it would be desirable for a farmer to know that the sanitizing system did not properly sanitize the milking system before the farmer started to use the milking system. Thus, Branton discloses a backup timer motor. Badura does not have something akin to the sanitizing system of Branton or a primary timer motor that is likely to fail, thus the basic premise behind the system of Branton has no appreciable application to the system of Badura. Thus, the logical leap the Examiner attempts to take simply is unjustifiable.

Rather than provide the required rationale based on logical uses of related technologies, the Examiner has taken completely disparate references directed toward unrelated technologies and combined them based on a hindsight-based rationale that is neither supported nor logical in view of the technological differences in the references. Such a conclusory rejection ignores the above noted guidance provided by the Supreme Court. The lack of a proper rationale makes it plain that the rejection does not meet the standard for making a *prima facie* case of obviousness and therefore the rejection of the pending claims should be reversed on this ground alone.

B. An Attempt to Modify Badura With Branton Would Lead to a Non-Functional Design and Therefore the Rejection of Claims 1-14 and 16-23 Lacks Support.

As noted above, the failure to provide a rationale for why the technologically different references should be combined makes it plain that the rejection is too conclusory to meet the standard promulgated by the Supreme Court. In addition to failing to provide a rationale for why Badura and Branton should be combined, the proposed attempt to modify Badura with Branton would lead to an inoperative combination. In other words, attempting to modify Badura with the system of Branton would cause the system of Badura to cease to function as intended.

In Branton, the length of the wash and rinse cycles was known, therefore it was relatively

simple to provide a timer motor that would end slightly after the two cycles were supposed to be complete. While the treatment cycle disclosed by Badura has nothing in common with the preparatory wash and rinse sanitizing cycle used in Branton, as noted above, the treatment cycle of Badura can also vary. In particular, Badura explains that the time of treatment may vary:

> The scan speed of the treatment beam depends on the particular intensity of the beam and the planned particle coverage. In order to ensure that the maximum scan speed is not achieved during the irradiation, the particle rate extracted from the synchrotron 5 is not permitted substantially to exceed the desired value. If, on the other hand, the rate falls distinctly short of that value, the total irradiation time is extended, the supervisory control and surveillance or monitoring system in that case optionally being operated in the range of very small input currents, which can adversely affect the accuracy of the beam detection. Accordingly, in the present therapy system, measurement and protocolling of the particle intensities in the synchrotron is provided in the upper intensity range and measurement and recording of the particle rate delivered to the irradiation site is provided for all levels of intensity for a plurality of energies over a few minutes.

Badura, Col. 7. Ln. 16-32 (emphasis added). Thus, the treatment time is not always known in advance but instead depends on the particle rate achieved. Therefore, attempting to use a timer as disclosed by Branton would cause the system of Badura to fail to work as intended because the timer would interfere with allowing the length of treatment to vary depending on the patient's needs and the timer would also prevent variations in the treatment time based on the measured particle rate of the ion-beam being applied. No support has been provided for how a person of skill in the art would modify the timer motor disclosed by Branton (which is a somewhat crude method of cutting off of power to the entire system) for use with the system of Badura. Applicants respectfully submit that is unclear how such a modification would even be possible, even with the benefit of improper hindsight reconstruction, without destroying the intended functionality of Badura. Thus, for this additional reason the rejection should be reversed.

C. The Proposed Modification of Badura With Branton Does Not Address the Recited Functionality and Therefore the Rejection of Claims 1-14 and 16-23 Lacks Support.

In addition to destroying the intended functionality of Badura, the proposed combination of Badura and Branton does not address the recited feature. In particular, the Examiner suggested that:

> One of ordinary skill in the art would have found it obvious to use a timer for timing the interval between the first termination request and the second redundant request because ion beam therapy may comprise residual particle counts. Badura et al suggests that high particle counts should trigger an alarm for switching off the beam and that the particle count may vary. See col. 11, lines 31-59.

Final Office Action, pg. 3-4 (emphasis added). These statements do not provide support for the suggestion that it would be obvious to initiate a cycle ON timer with an ON command, as recited in claims 1 or 11. Instead, the above discussion relates to a termination request. Thus, it appears that the Examiner has attempted to combine a cycle ON timer in Branton with a termination request in Badura to form something entirely different than what is claimed. Therefore, the rejection fails on two additional fronts: 1) it does not address the recited feature because what is recited in the claims is not a termination request, and 2) no support is provided for why the disclosure in Branton regarding the use of the timer motor should apply to the interval between two termination requests – particularly in view of the existence of a redundant shut-off system already included in Badura. In other words, the rationale for the combination of references is conclusory without the required support and logical underpinnings required. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741 (2007) ("To facilitate review, this analysis should be made explicit. *See In re Kahn,* 441 F.3d 977, 988 (C.A.Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of

obviousness").").

Furthermore, as noted above, the basis for using the second timer motor in the system of Branton was that the primary timing device was also a timer motor that could fail (the dirt and dust in a farm environment could readily cause the timer motor to get stuck or wear out, for example) and therefore it was beneficial to have a back-up timer motor to alert a farmer that the milking system had not been properly sanitized before the farmer started to milk the cows. There is simply no equivalent issue in the system of Badura (the Examiner has not pointed, for example, to a maintenance cycle in Badura that would be equivalent to the sanitizing system in Branton), thus the attempt to use the system of Branton to modify Badura is not supported.

D. No Support Has Been Provided For Why the Combination of Strul and Branton Is Believed to Render Claim 15 Unpatentable.

Claim 15 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Strul in view of Branton. Applicants have previously noted that no proper support has been given for why Strul can be said to render claim 15 obvious. For example, claim 15 depends from claim 11, which recites two components, and the Examiner did not provide a rationale for why Strul is believed to disclose the recited features of claim 11. Instead, the Office Action merely includes the following:

> One of ordinary skill in the art would have found it obvious to use the initiating cycle ON timer that is responsive to receiving the ON command signal as taught by Branton for providing safety to the device disclosed in Strul et al.
>
> Strul et al disclose software controlled limits for temperature, power, and impedance (that turn off power if exceeded), there are also redundant hardware controls, including comparators 90, 96, that turn off power if the maximum temperature or power is exceeded. One of ordinary skill in the art would have found it obvious to provide a timer for initiating the redundant hardware controls because temperature, power, and impedance have residual energy capacities that diminish with time to allow for a more accurate determination of whether they have been exceeded.

Final Office Action, pg. 5. As can be readily appreciated, this terse and conclusory rejection does not address the recited features of claim 11 or 15 or provide any support for why those features are believed to be present in Strul. Prior rejections also failed to provide the required support. Applicants respectfully submit it would not be obvious to adapt the radio frequency ablation method of Strul where the RF energy is controlled based on monitoring temperature and power to include all the features recited in claim 15. For example, there has been no support provided to show how Strul is believed to disclose a component that both could receive the signal and also is implantable. Plainly, the sanitizing system of Branton, which is intended to work with a milking system, does not help in this regard. Thus, the rejection is plainly deficient.

In addition to failing to disclose why Strul can be said to disclose the recited features of claim 15, there has also been no support provided for how a timer based on the system of Branton would be implemented in the system of Strul. The timer motor of Branton could not readily be inserted into the system of Strul. Furthermore, it appears that the desired "on time" in the system of Strul would vary depending on a number of factors such as the amount of tissue

being ablated, the type of tissue and the energy level being used. Thus, unlike the system of Branton where the sanitizing time was known, the "ON" cycle time for the system of Strul does not appear to be readily predictable. The Examiner provided no support for how the timer of Branton would apply in the face of these variables. The Examiner also failed to provide support for the conclusory suggestion that a timer would help account for the alleged diminished capacities. For example, the Office Action has failed to provide any support for the suggestion that the treatment disclosed by Strul is being applied for a long enough period to even need to be concerned with the alleged diminishing of energy capacities. Instead it appears that the entire rejection is conclusory without the required support, and therefore should be withdrawn.

VIII. Conclusion

The rejections contained in the Final Office Action of January 15, 2008 should be reversed for at least the reasons recited above. Reversal of the rejections is requested.

Respectfully submitted,

Date: June 9, 2008

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CLAIMS APPENDIX

1. A method for providing redundant back-up to ensure a treatment therapy provided by a medical device system is turned off comprising the steps of:

(a) receiving an ON command signal to activate delivery of the treatment therapy to a patient;

(b) in response to receiving the ON command signal, initiating a cycle ON timer to operate for a predetermined cycle ON time;

(c) delivering the treatment therapy to the patient;

(d) determining whether the cycle ON timer has expired prior to receiving an OFF command;

(e) if the OFF command is received, turning off the treatment therapy; and

(f) if the cycle ON timer has expired prior to receiving the OFF command, turning off the treatment therapy regardless of whether the OFF command signal is received.

2. The method of claim 1, further comprising the steps of:

(g) initiating a cycle OFF timer to operate for a predetermined cycle OFF time; and

(h) preventing delivery of the treatment therapy until either the cycle OFF timer has expired or the OFF command is received.

3. The method of claim 2, further comprising the steps of:

(i) if the cycle OFF timer has expired, reinitiating the cycle ON timer and delivering the treatment therapy to the patient; and

(j) if the OFF command is received, turning off the cycle OFF timer.

4. The method of claim 1, wherein the step of delivering comprises the step of delivering at least one treatment therapy selected from the group consisting of electrical stimulation, magnetic stimulation, drug infusion, and brain cooling.

5. The method of claim 1, wherein at least one of the steps is performed using discrete logic circuitry.

6. The method of claim 1, wherein at least one of the steps is performed by computer software.

7. The method of claim 1, wherein each of the steps are performed in a therapy delivery component of the medical device system.

8. The method of claim 1, wherein each of the steps are performed in a stimulation board of the medical device system.

9. The method of claim 1, wherein the cycle ON time is programmable.

10. The method of claim 1, wherein the cycle ON time is predefined.

11. A medical device system that provides redundant back-up to ensure a treatment therapy is turned off comprising in combination:

(a) a first component capable of transmitting an ON command signal to activate delivery of the treatment therapy to a patient and an OFF command signal to terminate delivery of the treatment therapy to a patient;

(b) a second component capable of receiving the ON command signal to deliver the treatment therapy to the patient and capable of receiving the OFF command to terminate delivery of the treatment therapy to the patient;

(c) a cycle ON timer within the second component, wherein, in operation, the cycle ON timer is activated in response to the second component receiving the ON command signal,

wherein the second component is also responsive to the cycle ON timer for causing termination of delivery of the treatment therapy in the event that the second component does not receive an OFF command from the first component for a period longer than a predetermined cycle ON time and during which time the treatment therapy is being delivered.

12. The medical device system of claim 11, wherein the first component is a physician programmer.

13. The medical device system of claim 11, wherein the first component is an external device.

14. The medical device system of claim 11, wherein the second component is a bedside device.

15. The medical device system of claim 11, wherein the second component is an implanted device.

16. The medical device system of claim 11, further comprising discrete logic within the second component for performing the steps of: (i) initiating the cycle ON timer to operate for the predetermined cycle ON time; (ii) determining whether the cycle ON timer has expired prior to receiving an OFF command; and (iii) if the cycle ON timer has expired prior to receiving the OFF command, turning off the treatment therapy regardless of whether the OFF command signal is received.

17. The medical device system of claim 16, wherein the discrete logic is configured to perform the following additional steps: (iv) initiating a cycle OFF timer to operate for a predetermined cycle OFF time; and (v) preventing delivery of the treatment therapy until either the cycle OFF timer has expired or the OFF command is received.

18. The medical device system of claim 17, wherein the discrete logic is configured to perform the following additional steps: (vi) if the cycle OFF timer has expired, reinitiating the cycle ON timer and delivering the treatment therapy to the patient; and (vii) if the OFF command is received turning off the cycle OFF timer.

19. The medical device system of claim 11, further comprising computer executable instructions within the second component for performing the steps of: (i) initiating the cycle ON timer to operate for the predetermined cycle ON time; (ii) determining whether the cycle ON timer has expired prior to receiving an OFF command; and (iii) if the cycle ON timer has expired prior to receiving the OFF command, turning off the treatment therapy regardless of whether the OFF command signal is received.

20. The medical device system of claim 19, wherein the computer executable instructions are configured to perform the following additional steps: (iv) initiating a cycle OFF timer to operate for a predetermined cycle OFF time; and (v) preventing delivery of the treatment therapy until either the cycle OFF timer has expired or the OFF command is received.

21. The medical device system of claim 20, wherein the computer executable instructions are configured to perform the following additional steps: (vi) if the cycle OFF timer has expired, reinitiating the cycle ON timer and delivering the treatment therapy to the patient; and (vii) if the OFF command is received turning off the cycle OFF timer.

22. The medical device system of claim 11, wherein the cycle ON time is programmable.

23. The medical device system of claim 11, wherein the cycle ON time is predefined.

EVIDENCE APPENDIX

-- NONE --

RELATED PROCEEDINGS APPENDIX

-- NONE --